products intended for use in the manufacture of blood and blood components or for the maintenance of data that personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion of further manufacture are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(h)]. This initiative was also described in a Federal Register (FR) notice dated August 31, 1994 (59 44991) [copy enclosed].

As a medical device manufacturer, you are currently required under the Act to register your establishment and list your devices. In addition, your manufacturing operations are required to be in compliance with CGMP for devices, and you must report adverse events and other problems as required by FDA's Medical Device Reporting (MDR) regulations. FDA's device registration and listing regulations appear at Title 21, *Code of Federal Regulations* (CFR), Part 807; CGMP regulations for devices appear at 21 CFR, Part 820; and the MDR regulations appear at 21 CFR, Part 803. These and other specific points relating to establishment inspections noted in the March 31, 1994, letter and the August 31, 1994, Federal Register notice remain unchanged.

In these documents, FDA stated that manufacturers of blood establishment computer software would be required to submit to the Center for Biologics Evaluation and Research (CBER) a premarket notification or application for premarket approval for each of their devices no later than March 31, 1995. The agency received numerous responses from organizations representing both software manufacturers and blood establishments. The principal concern expressed in these responses related to the requirements for premarket clearances or approval for blood establishment computer software products. The concerns included, but were not limited to, the difficulty of expeditious compliance with the requirement for premarket clearance or approval, the need for additional, detailed guidance to be used in the preparation of premarket submissions for these specific software products, and additional time needed to remove software from use by blood establishments in situations where a software manufacturer does not intend to seek premarket clearance or approval for the particular product.

After careful evaluation of the needs expressed by the software manufacturers and the impact of this regulatory initiative on blood establishments, the FDA has concluded that a one year extension of the March 31, 1995, deadline is warranted. Therefore, premarket submissions should be submitted to CBER no later than March 31, 1996. The extension period for premarket submissions does not, however, affect other responsibilities of the computer software manufacturers and distributors who are subject to the device provisions of the Act and implementing regulations as previously stated.

To effectively implement this important and complex regulatory program, the agency intends to work with industry to clarify the expectations concerning premarket submissions through issuance of guidance. We also plan to have a continuing dialogue with affected establishments and industry organizations.

Also, within this extension period, it is the FDA's expectation that vendors and blood establishments will cooperatively conduct all transitions from software products for which premarket clearance or approval will not be sought to software products for which premarket clearance or approval is being actively pursued. These transitions should also be conducted in an orderly and effective manner so that they have minimal impact on the blood establishment's operations as they relate to the identity, safety, purity, and quality of blood products. These transitions should also be completed by March 31, 1996.

If you do not intend to make a premarket submission as outlined in the August 31, 1994, Federal Register notice, this information should be promptly sent to: Center for Biologics Evaluation and Research (CBER), Division of Blood Applications (HFM–370), 1401 Rockville Pike, Rockville, MD 20852–1448. The information should include your intent to remove software from the market and identify the steps to be taken and the support to be provided during the time needed for users to efficiently transition to other products or software manufacturers by March 31, 1996.

If you intend to make a premarket submission and have not done so by September 30, 1995, we request that you notify CBER by letter of the specific progress made by that point in time, the work remaining to be completed, and the anticipated date of filing each applicable premarket submission if not completed and submitted by September 30, 1995.

If you have questions concerning: (1) the preparation of the establishment registration and device listing notification, contact Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ–220), at 301–443–6597, or (2) guidance for premarket submissions, contact Center for Biologics Evaluation and Research, Division of Blood Applications (HFM–370), at 301–594–2012. Please note that information regarding the content and format for premarket notification submission can be found at 21 CFR, Part 807, Subpart E.

Dated: September 26, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–24534 Filed 9–28–95; 11:22 am]

BILLING CODE 4160–01–F

Food And Drug Administration

[Docket No. 92N–0391]

Analysis of Adverse Reactions to Monosodium Glutamate (MSG); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Analysis of Adverse Reactions to Monosodium Glutamate (MSG),'' which the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) has prepared under a contract with FDA. As announced in the Federal Register of December 4, 1992, the agency requested that LSRO/FASEB undertake a reexamination of scientific data on possible adverse reactions to MSG.

ADDRESSES: ''Analysis of Adverse Reactions to Monosodium Glutamate (MSG)'' may be ordered from the Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20814. The cost of a single paper copy is $50. Payment may be made by check or money order. For telephone orders or further information on placing an order, call LSRO/FASEB at 301–530–7030.

FOR FURTHER INFORMATION CONTACT: Lawrence J. Lin, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3103.

SUPPLEMENTARY INFORMATION: In the Federal Register of December 4, 1992 (57 FR 57467), FDA announced that it had requested that LSRO/FASEB undertake a reexamination of scientific data on possible adverse reactions to MSG, under a contract (223–92–2185) with FDA. The announcement also solicited data and information and advised that there would be an open meeting, which was held on April 7 and 8, 1993, for public oral presentation of scientific data, information, and views. LSRO/FASEB completed this review and submitted to FDA a final report entitled ''Analysis of Adverse Reactions to Monosodium Glutamate (MSG)''. The agency is now announcing the availability of this final report.

Dated: September 25, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–24594 Filed 10-02–95; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following Heart, Lung, and Blood Special Emphasis Panel (SEP) meetings:

Name of SEP: Review on Infant Heart Surgery: CNS Sequelae of Circulatory Arrest.

Date: October 29, 1995.

Time: 8:10 p.m.

Place: Hyatt Regency Bethesda.

Contact Person: David M. Monsees, Rockledge II, Room 7178, Bethesda, Maryland 20892–7924, (301) 435–0270.

Purpose/Agenda: To review and evaluate grant applications.

Name of SEP: Review on Risk Factors in Early Human Atherogenesis.

Date: October 30, 1995.

Time: 8:30 a.m.

Place: Hyatt Regency Bethesda.

Contact Person: David M. Monsees, Rockledge II, Room 7178, Bethesda, Maryland 20892–7924, (301) 435–0270.

Purpose/Agenda: To review and evaluate grant applications.

These meetings will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; and 93.839, Blood Diseases and Resources Research, National Institutes of Health)

Dated: September 27, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–24561 Filed 10–2–95; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Allergy and Infectious Diseases Special Emphasis Panel (SEP) meeting:

Name of SEP: National Institute of Allergy and Infectious Diseases Special Emphasis Panel—National Cooperative Inner-City Asthma Study.

Date: October 23–25, 1995.

Time: 8:30 a.m.

Place: Holiday Inn Gaithersburg, 2 Montgomery Village Avenue, Gaithersburg, MD 20879.

Contact Person: Dr. Allen Stoolmiller, Scientific Review Administrator, 6003 Executive Boulevard, Solar Bldg., Room 4C05, Bethesda, MD 20892–7610, (301) 496–7966.

Purpose/Agenda: To evaluate and review individual grant applications.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Programs Nos. 93.855, Immunology, Allergic and Immunologic Diseases Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health)

Dated: September 27, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–24558 Filed 10–2–95; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Deafness and Other Communication Disorders; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting:

Name of Committee: Communication Disorders Review Committee.

Date: October 18–20, 1995.

Time: 8 am–5:30 pm.

Place: National Institutes of Health, Natcher Building, Rooms C–1/C–2, 9000 Wisconsin Avenue, Bethesda, MD 20892.

Contact Person: Craig A. Jordan, Ph.D., Scientific Review Administrator, NIDCD/DEA/SRB, EPS Room 400C, 6120 Executive Boulevard, MSC 7180, Bethesda, MD 20892–7180, 301–496–8683.

Purpose/Agenda

To review and evaluate grant applications. The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. The applications and/or proposals and the discussion could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which could constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.173 Biological Research Related to Deafness and Communication Disorders)

Dated: September 27, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–24559 Filed 10–2–95; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meeting of the Board of Scientific Counselors

Pursuant to Pub. L. 92–463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), November 1–3, 1995, National Institutes of Health, Building 5, Room 127, Bethesda, Maryland 20892.

The meeting will be open to the public on November 1 from 7 p.m. to 7:30 p.m. for discussions of policies of the NIDDK Intramural Research Program. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sec. 552b(c)(6), Title 5, U.S.C. and sec. 10(d) of Pub. L. 92–463, the meeting will be closed to the public on November 1 from 7:30 p.m. to 10 p.m.; November 2 from 8:30 a.m. to 6 p.m. and on November 3 from 9 a.m. to adjournment for the review, discussion and evaluation of individual intramural programs and projects conducted by the NIDDK, including consideration of personnel qualifications and performance, the competence of individual investigations, and similar items, disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

A summary of the meeting and roster of members will be provided, upon request, by the Committee Management Office, National Institute of Diabetes and Digestive and Kidney Diseases, Building 31, Room 9A07, Bethesda, Maryland 20892.

For any further information, and for individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, please contact Dr. Allen Spiegel, Scientific Review Administrator, Board of Scientific Counselors, National Institutes of Health, Building 10, Room 9N–222, Bethesda, Maryland 20892, (301) 496–4128, prior to the meeting.

(Catalog of Federal Domestic Assistance Program Nos. 93.847–849, Diabetes, Endocrine and Metabolic Diseases; Digestive Diseases and Nutrition; and Kidney Diseases, Urology and Hematology Research, National Institutes of Health)

Dated: September 27, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–24560 Filed 10–2–95; 8:45 am]

BILLING CODE 4140–01–M